

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

*THIS DOCUMENT RELATES TO:  
ALL CASES*

**MDL No. 2804**

**Case No. 17-md-2804**

**Hon. Dan Aaron Polster**

**McKESSON'S REPLY MEMORANDUM IN SUPPORT OF  
MOTION TO COMPEL PRODUCTION OF THE  
OHIO AUTOMATED Rx REPORTING SYSTEM DATABASE**

**INTRODUCTION**

The opposition filed by the State of Ohio Board of Pharmacy ("the Board") fails to appreciate the critical discovery needed to defend against Plaintiffs' sprawling claims that Defendants' marketing and distribution practices were the factual and proximate causes of myriad opioid addictions and deaths, and of billions of dollars in past and recurring claimed damages.<sup>1</sup>

This discovery dispute boils down to two main issues: (1) whether the Court should adhere to the guiding principles it invoked to decide Plaintiff's request for the U.S. Drug Enforcement Agency's ("DEA") Automated Records and Consolidated Orders System ("ARCOS") database in now considering McKesson's request for the OARRS database (the Court should); and (2) whether the Board has met its burden under the Federal Rules of Civil Procedure to demonstrate that the public interest weighs against production of the confidential database in this very complex litigation (the Board has not). For reasons described in McKesson's initial motion and in Part I

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<sup>1</sup> McKesson understands that a subset of Defendants intends to join in supporting this motion.

below, the Court should immediately order production of the OARRS database pursuant to a Protective Order and the conditions set forth below or Defendants will be materially prejudiced at trial.

The Board's opposition has a significance that goes beyond this discovery dispute. As explained in Part II, the Board admits that Plaintiffs' theory of liability against Defendants is without merit.

### **ARGUMENT**

#### **I. THE COURT SHOULD ORDER PRODUCTION OF THE OARRS DATABASE UNDER A PROTECTIVE ORDER**

##### **A. McKesson's Subpoena Has Always Been Understood to Request the OARRS Database**

The Board suggests that McKesson's motion should fail in the first instance because its request for documents "from" the database was never a formal request for "production of the database" itself.<sup>2</sup> This argument is without merit. When a subpoena defines "documents" broadly to include data or other electronically stored information, it does not matter that the subpoena itself does not explicitly request production of data. *See Selee Corp. v. McDanel Advanced Ceramic Techs., LLC*, No. 1:15-CV-00129-MR, 2016 WL 4546446, at \*2 (W.D.N.C. Aug. 31, 2016) (granting Plaintiff's Motion to Compel electronic data originally requested as "documents relating to the conception, selection, and adoption of the terms 'engineered ceramics.'"); *See also* *S.E.C. v. Collins & Aikman Corp.*, 256 F.R.D. 403, 417 (S.D.N.Y. 2009) ("Regardless, even if the Plaintiff had not so specified, "[i]t is by now well established that electronically stored information is subject to discovery."); *McPeck v. Ashcroft*, 202 F.R.D. 31, 32 (D.D.C. 2001) ("During

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<sup>2</sup> Opp'n at 6.

discovery, the producing party has an obligation to search available systems for the information demanded).

McKesson's July 11 Subpoena sought, *inter alia*, "all *documents* reflecting the Board's receipt of data or information from the Ohio Automated Rx Reporting System."<sup>3</sup> Defendants specifically defined "documents" to mean any form of collected data, including but not limited to electronically stored information.<sup>4</sup> There has never been a doubt that Requests 11 and 12 seek the contents of the OARRS database. Indeed, the Board's initial August 3rd objections demonstrate that it understood the subpoena as requesting the entire OARRS database,<sup>5</sup> and meet-and-confer discussions since then have always focused on the database.

**B. Adequate Protections for Treatment of Patient Health Information Are Already in Place**

Like ARCOS, OARRS contains confidential information highly relevant to the resolution of critical issues in this litigation, and the Board—as did the DEA—cites various privacy and investigative concerns in objecting to a validly issued subpoena. This Court has already rejected these arguments.<sup>6</sup>

McKesson understands that OARRS contains medical information that is private in nature and ordinarily protected by state and federal law. However, this Court has entered multiple Protective Orders to allow relevant discovery while safeguarding personally identifiable information and other confidential materials.<sup>7</sup> The Plaintiffs have produced identified medical,

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<sup>3</sup> Doc. #1221-3; Ex. A (emphasis added).

<sup>4</sup> *Id.*

<sup>5</sup> *See* Doc. #1221-4; Ex. B.

<sup>6</sup> *See* Doc. 233, p. 8.

<sup>7</sup> *See* Doc. 167, 800, 1051.

autopsy, and prescription claims data pursuant to these protections.<sup>8</sup> Nevertheless, McKesson has in good-faith attempted to negotiate an *additional* order to ease the Board’s concerns with sharing the OARRS database, but its attempt has gone largely ignored. McKesson stands ready to continue to negotiate such additional protections as may be reasonably necessary after the Court rules that the Board must produce the OARRS database.

This Court considered and rejected arguments punctuated by similar concerns that the DEA raised in its initial objections to producing ARCOS,<sup>9</sup> finding that the database is “critical not only to all of plaintiff’s claims, but also to the Court’s understanding of the width and depth of this litigation” because it could show “precisely which manufacturers sent which drugs to which distributors” and “which distributors sent which drugs to which pharmacies and doctors.”<sup>10</sup> In fairness to Defendants and to aid the fact-finder, the Court should allow Defendants the similar opportunity to show which doctors prescribed which drugs to which patients, what the trends and patterns were, and what information the Board and Plaintiffs’ agents authorized to view the database knew about it and when they knew about it.<sup>11</sup> Plaintiffs have used the ARCOS data to dismiss some Defendants they had sued initially, and to add some Defendants not initially sued. Independent analysis of the OARRS data will identify alternative causes of diversion that Plaintiffs should have named in their complaint in the first place and to whom fault is properly allocated. *See* Ohio Rev. Code § 2307.23(C). To the extent any entity can be held liable for causing the

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<sup>8</sup> See Doc. 1051, p. 2-3. (“All parties shall safeguard and maintain the confidentiality of this data pursuant to the terms of the HIPAA protective order and shall limit disclosure of this identified claims data to attorneys and experts for the parties, unless otherwise ordered by the Court.”).

<sup>9</sup> The DEA’s initial objections were raised in *City of Cincinnati v. AmerisourceBergen Drug Corp.*, case no. 2:17-VC-713 (S. D. Ohio), before its removal to the MDL.

<sup>10</sup> Doc. #233, p. 8.

<sup>11</sup> *See* Mtn. to Compel at 12–13.

opioid epidemic, fault for the injuries alleged in the complaint should be apportioned among all those who are at fault, including nonparties. *See id.* The OARRS database will allow analysis of the entire picture—prescribing and dispensing, as well as distribution—rather than just the distribution part of the equation that Plaintiffs were provided via ARCOS.

**1. State and Federal Law Do Not Bar Disclosure of OARRS Under A Protective Order**

This Court has already addressed concerns regarding the production of personal confidential information. It recognizes that the confidential nature of the information does not render it less relevant in this litigation—litigation ensuing from a declared opioid epidemic and national emergency that naturally and necessarily implicates the drug use of millions of individuals. The Board offers no new explanation that would justify deviation from the Court’s approach thus far.

In support of its argument that it is precluded from producing the OARRS database, the Board cites 42 U.S.C. § 290dd-2 (“Part 2”). Part 2 protects from disclosure the records of drug treatment received through federally-funded programs. The parties have recognized throughout the litigation that Part 2 is a potential impediment to the development of a full and complete factual record. As such, the parties have worked together to reach an agreement that records and data that reflect addiction treatment or references to, and prescriptions for, Suboxone (buprenorphine) may be produced in an anonymized fashion. These data and records are subject to the same strict protective order proscriptions as other Patient Health Information produced in the course of this litigation. Simply put, Part 2 is not a barrier to production of the OARRS database. Rather, under the adequate protections that already exist, the Board could produce this subset of data that potentially implicate addiction treatment in a manner that obscures the patient’s identity.

As to the argument that Ohio Rev. Code § 4729.80(A) and § 4729.86(B) also prohibit disclosure of the database<sup>12</sup>, McKesson refers the Court to its opening brief for authority on the inapplicability of state law confidentiality provisions to discovery in federal court.<sup>13</sup> McKesson is not seeking substance abuse treatment records nor are they seeking full-scale public disclosure of confidential PDMP data.

Rule 26 provides that a Protective Order may, among other things, forbid requested discovery or disclosure, specify the terms for discovery or disclosure, forbid inquiry into certain matters or limit the scope of discovery or disclosure to certain matters, or require that confidential information not be revealed or that it be revealed only in a specified way. *See* Fed. R. Civ. P. 26(c)(1)(A)–(H). Indeed, otherwise-discoverable private medical information of non-parties can be protected adequately by crafting an appropriate Protective Order limiting access to the information. *See Scott v. Clarke*, No. 3:12-CV-00036, 2013 WL 6158458, at \*7 (W.D. Va. Nov. 25, 2013) (citing *Watson v. Lowcountry Red Cross*, 974 F.2d 482, 489–92 (4th Cir. 1992); *Oslund v. United States*, 128 F.R.D. 110 (D. Minn. 1989). *See also Shovah v. Mercure*, No. 2:11-CV-201, 2013 WL 12226890, at \*3 (D. Vt. Oct. 30, 2013) (ordering medical and mental health records to be produced subject to the protective order that they be used only for purposes of this litigation).

The Board cites no proper authority justifying its argument that the patient information McKesson seeks is *non-discoverable* in this litigation. It cites *Whalen v. Roe* as support for its claim that the millions of Ohio patients have a right to privacy in their prescription data. But this common sense proposition is not in dispute. In recognizing the privacy implications inherent in the construction of PDMPs, *Whalen* did not go as far as to forbid discovery of PDMP data under

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<sup>12</sup> Opp’n at 10.

<sup>13</sup> *See* Mtn. to Compel at 14–15.

a court order. Indeed, this Court has already ordered production of private medical and prescriptions claims data under a court order. *Whalen* also did not address how the significant public interest in this litigation might affect the balancing of privacy interests with disclosure subject to a protective order. Defendants have had to disclose information that is treated as confidential because of its competitive significance, and even Plaintiffs have had to produce personnel files that they would ordinarily keep secure. The Board's suggestion that the ordinary restrictions on the disclosure of the OARRS database should apply fails to appreciate the Court's, and the fact-finder's, role in understanding the scope of this litigation and fails to appreciate the concept of discovery more generally.

## **2. Law Enforcement Privilege Does Not Apply to the OARRS Database**

The Board raises issues of law enforcement privilege similar to those this Court has already entertained and rejected. For the first time, the Board maintains that “at its core, the OARRS database is a law enforcement database,”<sup>14</sup> contradicting the deposition testimony of the Board's OARRS Director, Chad Garner, that OARRS “is a healthcare tool first, [and] a law enforcement tool second.” It is obvious that OARRS serves as much more than a law enforcement tool. Ohio Rev. Code § 4729.80 authorizes disclosure of the data to *several* users, most of whom are not law enforcement personnel. As explained in McKesson's opening brief, the database does *not* include

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<sup>14</sup> Opp'n at 13.

any investigative materials such as questions and observations of law enforcement. It does *not* include any analysis or work product.<sup>15</sup> It contains factual data only.

The law enforcement privilege prevents disclosure of law enforcement *techniques* and *procedures*. *United States v. Garner*, Case No. 3:16-cr-88, 2017 U.S. Dist. LEXIS 44757, at \*3 (S.D. Ohio Mar. 27, 2017) (emphasis added) (examining the government’s refusal to produce the “exploit” or “server component” of the Network Investigative Technique used to collect a computer’s IP address and transmit it back to the government). Under *Garner*, the Board’s claim might fare better if McKesson was seeking the computer code used to generate the OARRS internal investigative reports, but it is not.

Invoking the law enforcement privilege “requires: (1) a formal claim of privilege by the ‘head of the department’ having control over the requested information; (2) assertion of the privilege based on actual personal consideration by that official; and (3) a detailed specification of the information for which the privilege is claimed, with an explanation why it properly falls within the scope of the privilege.” *Landry v. F.D.I.C.*, 204 F.3d 1125, 1135 (D.C. Cir. 2000). The party asserting the privilege bears the burden of establishing its applicability:

To meet that burden, the party must first establish that the documents contain information the privilege is intended to protect. The privilege is intended to protect information pertaining to law enforcement techniques and procedures, information that would undermine the confidentiality of sources, information that would endanger witness and law enforcement personnel or the privacy of individuals involved in an investigation, and information that would otherwise interfere with an investigation.

*United States v. Quebe*, 2017 WL 279539 at \*13 (S.D. Ohio 2017) (internal citations and quotations omitted). A corollary to the requirement that the party withholding information must

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<sup>15</sup> If the Board can truly demonstrate that release of certain, specific data would interfere with a pre-existing and ongoing enforcement proceeding, it can move the Court for relief from release of that particular data (and make an *in camera* submission, if necessary). See Doc. #233, p. 17.



provide a “detailed specification” of the materials is that *ipse dixit* assertions and across-the-board claims do not suffice. *See United States v. Wey*, 252 F. Supp. 3d 237, 251 (S.D.N.Y. 2017); *Alexander v. F.B.I.*, 186 F.R.D. 154, 167 (D.D.C. 1997).

To be taken seriously, the Board’s law enforcement privilege claims must at least attempt to comply with the applicable legal standard and procedural requirements. To date, no formal claim has been made by an official based on personal consideration, and no specifics about the information for which the privilege is claimed have been provided.

Even where a party has established a valid law enforcement privilege claim, courts have found that production of law enforcement privileged information on an “Attorneys’ Eyes Only” basis is appropriate. *See Floyd v. City of New York*, 739 F. Supp. 2d 376 (S.D.N.Y. 2010) (finding production of law enforcement privileged information on an Attorneys’ Eyes Only basis struck a “sensible balance” between plaintiffs’ compelling need for the information and the sensitivity of the materials). Where, as here, the preliminary showing required to demonstrate the applicability of the privilege has not been made in the first place, a Protective Order that limits disclosure to attorneys and their experts provides more than sufficient protection.

### **3. McKesson Cannot Obtain Much of the Same Information From Other Sources**

The Board’s suggestion that McKesson should have to cobble together the same data by issuing multiple subpoenas to the universe of physicians, pharmacies, benefit managers, and the like is unreasonable, if not absurd. This Court has already recognized that “it is not a valid objection to insist the data is available elsewhere, in small pieces.”<sup>16</sup> The breadth and depth of the data Defendants need to defend against Plaintiffs’ claims is held *only* by Board.

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<sup>16</sup> Doc. #233, p. 19.

**C. The Public Interest Weighs In Favor of Production of the OARRS Database**

Finally, as the party refusing production, the Board has failed to meet its burden to demonstrate that the discovery of confidential prescription data, under the strictures of a Protective Order, will significantly harm Ohio residents or jeopardize ongoing investigations. It argues that Ohioans have a right to privacy in this information and that McKesson has cited “no reason compelling enough” to overcome this interest.<sup>17</sup> To the contrary, McKesson’s request for the OARRS database is driven by similar justifications that this Court recognized as supporting Plaintiffs’ request for the ARCOS database. Plaintiffs requested the ARCOS data so they could discover how and where the opioid epidemic grew and this Court recognized production of the ARCOS data as a “reasonable” means to that end.<sup>18</sup> The Special Master already has determined that Defendants are “entitled” to receive all medical and prescription claims data associated with opioid prescriptions in order to link the patients’ information across the multiple databases and data sources.<sup>19</sup> Defendants seek the OARRS data to further explore and explain that link.

In response to Plaintiffs’ allegations, McKesson and its Co-Defendants assert that the opioid epidemic was caused by diversion that occurred at or after the prescribing and dispensing stage (and by the enormous increase in the abuse of highly dangerous illegal drugs, notably including heroin and fentanyl analogues). Because no other source contains all of the necessary prescribing and dispensing information to establish this aspect of its defense, McKesson’s request, too, is a reasonable means to that end. OARRS prescription data will allow Defendants and this

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<sup>17</sup> Opp’n at 18.

<sup>18</sup> See Doc. #233, p. 21.

<sup>19</sup> Doc. #1051, p. 2.

Court to assess the prescribing and dispensing side, which will also demonstrate the significant medical need for prescription opioid medications in Ohio.

The Board characterizes McKesson's motion as a "fishing expedition." Yet this Court has recognized that it is "important to obtain data that allows the parties to understand not only the identity of each potential defendant, but the extent to which each defendant and potential defendant engaged in the alleged [activity], which can only be revealed by all of the [ARCOS] data."<sup>20</sup> As the only entity that can produce the database that reveals all of the critical prescribing and dispensing information, the Board should be required to produce that information.

**D. There is No Legitimate Reason to Limit Production to Data From Two Counties**

McKesson and the Board agree that the OARRS database is highly relevant in this action. Indeed, Plaintiffs rely on the OARRS data to support the claims alleged in their Complaint. *See* Sec. Am. Compl. ¶¶ 709–713. The Board's suggestion that it might better entertain a request for data limited to Cuyahoga and Summit Counties, as described in its opposition, is disingenuous. The Board already prepares and produces state-wide data for researchers in the form of extraction data so there is no legitimate burden claim to be made. Instead, the only issue to be decided is not the breadth of McKesson's request but rather the adequacy of any protection to be given to the OARRS data. That issue has been fully addressed above and in McKesson's opening brief.

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<sup>20</sup> *Id.* at 15.

## II. THE BOARD BELIES PLAINTIFFS' THEORY OF LIABILITY AGAINST DISTRIBUTORS

The Board's assertions contradict Plaintiffs' theory of liability against Defendants. Plaintiffs' premise is that Defendants shipped too many opioid pills to Ohio in alleged breach of their regulatory and common law duties and they knew or should have known that the quantity of opioids far exceeded what was medically necessary. Sec. Am. Compl. ¶¶ 502 (defendants "flood[ed] Ohio with more opioids than could be used for legitimate medical purposes"); 689 (citing OARRS data and alleging that "[p]ublically available data suggests distribution of opioids to Summit County exceeded reasonable medical use"); 714 (defendants "funnel[ed] so many opioids into Summit County that they could only have been delivering opioids for diversion and illicit use"). The Board admits that Defendants could not have known whether the quantity of opioid medications ordered by Ohio pharmacies exceeded what was medically necessary because the "[t]he decision to prescribe opiate medications lies with the medical practitioner who evaluates a patient. *Without the medical records of a specific individual, it is impossible to determine if any specific prescription was even medically improper, let alone criminal.*"<sup>21</sup> But Defendants do not have in the ordinary course of their business access to any patient's medical records; indeed as the Board points out federal privacy laws prevent Defendants from even knowing to which patients opioids are prescribed and why.<sup>22</sup> The Board's statement—an assertion of what it deems self-evident—means Defendants did not have the information essential to determine whether the amount of opioid medications ordered by their pharmacy customers were for medically necessary purposes or not. In other words, Defendants could not have known whether the amounts ordered by Ohio pharmacies "exceeded reasonable medical use."

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<sup>21</sup> Opp'n at 17. (emphasis added).

<sup>22</sup> Opp'n at 8.

The Board goes on to contend that “[a]s to whether any particular prescription was improper, that information is best obtained from criminal records, state licensure bodies and, perhaps, records of civil suits.”<sup>23</sup> But Defendants have no visibility into the doctor-patient relationship and would have had no basis to search such records when deciding to fill pharmacy orders. Thus, they could not have known that any particular prescription—much less whole orders—was “improper” and for a medically unnecessary purpose.

### **CONCLUSION**

Granting McKesson’s request serves the public’s interest in this litigation and establishes a level playing field for Defendants. The Board has offered no justification sufficient to excuse its obligation to produce relevant information under Rule 45, especially when compared to the arguments unsuccessfully interposed by the DEA against production of the ARCOS database and by Plaintiffs against the production of medical and prescription claims data. For the above stated reasons, and for such other good cause the Court may discern, McKesson requests that the Court grant its Motion to Compel.

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<sup>23</sup> Opp’n at 17.

Date: December 18, 2019

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**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record and via email to counsel for the State of Ohio Board of Pharmacy on January 18, 2019.

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